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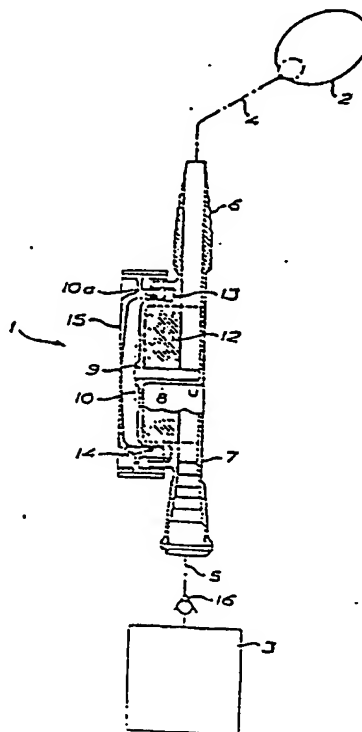
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(54) Title: A URINE DRAINAGE DEVICE PERMITTING TRAINING OF THE BLADDER

(57) Abstract

A urine drainage device permitting training of the bladder and comprising a catheter connectable to the bladder and communicating with a collection bag. The primary object of this invention is to provide a urine drainage device which is simple and reliable and which allows an effective bladder-training on patients confined to bed as well as other patients. To achieve this primary object the urine drainage device comprises a valve (1) for controlling the connection between the catheter (4) and the collection bag (3). The valve body (10) of the valve being arranged at the inlet (8) of the valve such that the inlet (8) is closed, unless a predetermined pressure is reached in the inlet and which pressure is capable to open said inlet and to keep said inlet opened to a pressure being substantially below the opening pressure of the valve (1).



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## A URINE DRAINAGE DEVICE PERMITTING TRAINING OF THE BLADDER

This invention relates to a urine drainage device permitting training of the bladder and comprising a catheter connectable to the bladder and communicating with a collection bag.

5 In the treatment of patients suffering from urine incontinence it is of great importance that the normal function of the bladder is re-established if possible, e.g. subsequent to a disease which has interfered with the normal function of the bladder. If the bladder is  
10 not allowed to expand by accumulating urine, there is a great risk of the bladder being shrunk, which means that the normal function of the bladder can never be re-established. This in turn means that the ability of the bladder to accumulate urine is almost completely  
15 lost and that the urine has to be continuously drained to a collection bag e.g. by means of a catheter.

Especially in geriatric hospital treatment, incontinence pads are widely used and recently disposable incontinent diapers as well. This treatment of the in-  
20 continent patients imposes strain on the nursing staff involved because it is necessary repeatedly to change the incontinence pads or diapers in order to achieve a humane treatment of these patients. Even if a normal function of the bladder for age or other reasons can  
25 never be re-established, it is of great importance that the accumulating ability of the bladder is maintained to relieve the strain imposed on the nursing staff, because the discharge of urine then could be fairly well controlled.

30 Devices of several different types for use in connection with bladder-training of incontinence patients have been suggested. The Swedish patent specification 389,803 discloses one type of such device. This device requires, as most existing devices for bladder-  
35 training do, the use of a catheter usually connected to

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5 a urine collection bag. Devices are also known which are provided with a pressure sensing system controlling the clamping of the catheter which is clamped until a predetermined pressure is reached in the bladder/catheter, the catheter then being relieved to allow drainage of the bladder.

None of these prior art devices meets reasonable requirements concerning a simple and reliable function; they are complicated as to construction and handling.

10 It is a primary object of this invention to provide a urine drainage device which is extremely simple and reliable and which allows an effective bladder-training on patients confined to bed as well as other patients.

15 It is a further object of this invention to provide a urine drainage device permitting an automatic drainage of the bladder when a predetermined maximum pressure in the bladder has been reached.

20 A still further object of this invention is to provide a urine drainage device which simultaneously forms a bacteriological barrier, i.e. prevents a urine back flow from the urine drainage device to the bladder.

25 Yet another object of this invention is to provide a urine drainage device allowing an automatic drainage of the bladder at a pre-set maximum pressure or a predetermined accumulated amount of urine in the bladder.

30 Another object of this invention is to provide a urine drainage device comprising few movable parts, the handling and using of which do not require much attention from the nursing staff and which in many cases can be operated by the patient himself.

35 A still further object of this invention is to provide a urine drainage device which may well be used also by such patients, whose normal function of the bladder will never be regained, the normal function of the blad-

der being imitated by using or maintaining the maximum capacity of the patient's bladder, i.e. the ability thereof to accumulate urine.

To achieve the foregoing objects and in accordance with the purpose of the invention, as embodied and  
5 broadly described herein, the urine drainage device according to the invention comprises a valve for controlling the connection between the catheter and the collection bag said valve including an inlet connected to the  
10 catheter, an outlet connected to the collection bag, and a valve body controlling the connection between the inlet and the outlet said valve body being arranged to keep the inlet closed by a resilient force and to open the inlet when a predetermined pressure is reached in  
5 the inlet, and being arranged at the inlet such that a pressure in said inlet substantially below the opening pressure of the valve, is capable of keeping said valve body in the opened position until said resilient force exceeds a force acting on the valve body, and provided  
10 by the fluid pressure in the inlet.

The resilient force acting on the valve body can be obtained by using a valve in which the valve body proper is arranged as a cup spring (Belleville spring), e.g. as disclosed in U.S. patent specification No.  
25 2,585,863, wherein the valve body has a flat characteristic and provides a certain resetting force towards the inlet when the valve body is in the open position thereof.

It is of course possible to arrange the valve body  
30 as a piston, the resilient force of which is provided by means of mechanical spring means, only part of the piston area being exposed to the inlet pressure of the valve when the valve is in a closed position.

Other arrangements of the valve are possible. Thus,  
5 a resilient diaphragm can be arranged to contact and co-



ver the inlet resiliently, whereby a further resilient force towards the inlet is applied on the diaphragm.

However, in a preferred embodiment of the invention one movable element only is used in the valve.

5 Said element forms the valve body and comprises a resilient diaphragm partially defining a chamber into which the outlet opens, said diaphragm contacting a sealing bead surrounding the inlet, to form a fluidtight seal below a certain maximum fluid pressure in the inlet.

10 The valve constituting part of the urine drainage device preferably comprises a circular valve housing in which the inlet is arranged centrally and which defines together with the diaphragm the chamber into which the outlet opens. The diaphragm is tightened over the valve  
15 housing to contact resiliently the sealing bead surrounding the opening of the inlet to the chamber.

An increase of the resilient force acting against the inlet can be achieved simply by arranging peripheral screwthreads or grooves on the circular valve housing, a lid formed with co-operating screwthreads or  
20 shoulders engaging said housing, provided that the peripheral edge portion of the resilient diaphragm engages the lid in such a way that the diaphragm is tightened when the lid is screwed onto the valve housing.  
25 ing.

Preferably, fastening means integral with the valve housing are used to secure the valve to the patient's body by anchoring bands or directly to the clothes of the patient by safety-pins or the like.

30 The accompanying drawing, which is incorporated in and constitutes a part of this specification, illustrates one embodiment of the invention showing the simplest variant of the valve wherein a single movable element is provided, and together with the description  
35 serves to explain the principles of the invention.

FIG. 1 in the drawing is an axial cross sectional view of a valve connected to a catheter and a collection bag, and

FIG. 2 is an elevational view of the valve according to FIG. 1.

The urine drainage device according to the invention comprises a valve 1 connected between a bladder 2 and a collection bag 3 through a connection 6 and a catheter 4, and a connection 7 and a conduit 5, respectively.

The valve 1 comprises a circular valve housing 12 provided with internal screwthreads 13 co-operating with external screwthreads on a circular lid 15. In the lid 15 an internal peripheral groove 14 is provided, into which a bead-formed peripheral edge portion 10a of the diaphragm engages. Thus, rotation of the lid 15 on the valve housing 12 effects the tightening of the diaphragm onto the valve housing. In the valve housing there is an inlet 8 and an outlet 11. An annular sealing bead 9 surrounds the opening of the inlet 8. The lid 15 may be partially perforated, but in any case must protect the diaphragm 10 against external influence which may cause malfunction of the valve.

Urine is drained to the conduit 6 and the inlet 8 through the catheter 4, and will exert a pressure in said inlet 8. As the resilient diaphragm 10 resiliently contacts the sealing bead 9 the inlet 8 is closed but when the fluid pressure in the inlet reaches a certain level, which is able to exert a force on the portion of the diaphragm, surrounded by the sealing bead 9, which exceeds the bearing force of the diaphragm, the diaphragm will be lifted from the sealing bead 9. In this position of the diaphragm the area of the diaphragm exposed to the fluid pressure will be large as compared with the area of the diaphragm surrounded by

the sealing bead 9, which means that the resulting force exerted by the fluid pressure on the diaphragm is able to keep the diaphragm away from the sealing bead also when the fluid pressure in the inlet 8 decreases during drainage of the bladder.

The outlet 11 is necessarily located above the inlet 8 to evacuate the air in the chamber when a fluid flow through the valve 1 is initiated. A fluid flow connection is established between the inlet 8 and the outlet 11 of the valve 1 as long as the pressure in the inlet 8 is sufficient to exert a force on the diaphragm, which exceeds the counteracting force exerted by the diaphragm. When the fluid pressure acting on the major area of the diaphragm, has decreased to a certain level, the diaphragm returns by resiliency to a position wherein it co-operates again with the sealing bead 9 to form a fluidtight seal. Thus, the connection between the inlet and the outlet of the valve is interrupted.

The opening pressure and the closing pressure of the valve may be varied within wide limits by suitable choice of the resiliency of the diaphragm material and, above all, by dimensioning the areas of the diaphragm exposed to fluid pressure, i.e. on one hand, the area surrounded by the sealing bead 9 and, on the other hand, the total area of the diaphragm exposed to fluid pressure when the valve is in its open position. In the disclosed embodiment of the invention said total area comprises a circular area, the diameter of which corresponds substantially to the diameter of the valve housing 12.

Axial adjustment of the lid 15 over the valve housing 12 means that the bearing pressure of the diaphragm exerted on the sealing bead 9 will be increased. Thus, this means that an increased fluid pressure must be



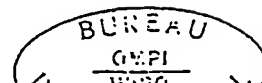
reached in the inlet 8 in order to exert a force sufficient to lift the diaphragm from the sealing bead 9.

The incontinent patient using the urine drainage device of this invention will recognize a need to urinate, since the muscles controlling the bladder will be influenced during the continuous accumulation of urine in the bladder in an amount sufficient to create a predetermined fluid pressure in the inlet of the valve prior to the automatic opening of the valve. When this need becomes too urgent, the patient may create a strain and thereby further increase the pressure onto the bladder. This increased pressure may be enough to allow the opening of the valve. Thus, ingenious enuresis may be imitated to a great extent by a patient using the urine drainage device of this invention.

The need of rinsing the bladder may not be necessary when using a urine drainage device of this invention. Today it is often necessary to rinse the bladder when the urine is continuously drained from the bladder, i.e. when the muscles normally controlling the bladder are not stimulated.

The reduced need of rinsing the bladder can be explained by the fact that the valve 1 permits an extraordinarily rapid movement of the diaphragm 10 away from the sealing bead 9, which means that the existing maximum fluid pressure within the bladder creates an initial turbulent fluid flow out of the bladder. Such turbulent fluid flow sustains the evacuation of heavy urine products from the bladder, including such urine products as exist below the outlet of the catheter 4 inserted into the bladder 2.

Preferably, the lid 15 of the valve is provided with e.g. three distinct setting positions, which may be indicated by symbols, - one for use in bed, one for use when the patient is allowed to move in upright po-

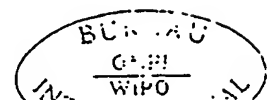


sition, and one creating a further increased opening pressure on the valve, which may be necessary to prevent a too early discharge of urine if the patient is suffering from coughing. When the patient coughs, this can result in an increased pressure in the abdominal cavity creating an unintended pressure on the bladder, sufficient to open the valve.

To prevent a back flow of urine i.e. from the collection bag 3 to the bladder 2, which may occur when an external pressure is exerted onto the bag, a check valve 16 is preferably arranged between the outlet 11 of the valve 1 and the inlet of the bag 3.

It will be apparent to those skilled in the art that various other modifications and variations in addition to those mentioned above could be made in the urine drainage device of the invention without departing from the scope and spirit of the invention.

Thus, it is possible to arrange the resilient diaphragm stationary around the periphery of the valve housing and with a constant bearing pressure against the sealing bead, which pressure can be exceeded by a low fluid pressure in the inlet of the valve. The diaphragm is arranged to be retained at its closing position towards the sealing bead by exerting an external force on the diaphragm, which force can be obtained by mechanical spring means arranged at the inside of the lid. This external force may be transferred to the diaphragm via a stiffened portion of the diaphragm. A setting of the opening pressure of the valve may easily be obtained by using the co-operating threads of the valve housing and the lid, respectively. Preferably, the mechanical spring means are integral with the lid.



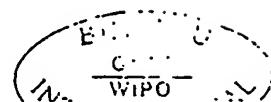
## CLAIMS

1. A urine drainage device permitting training of the bladder and comprising a catheter connectable to the bladder and communicating with a collection bag,  
5 c h a r a c t e r i z e d in that the urine drainage device comprises a valve (1) for controlling the connection between the catheter (4) and the collection bag (3) said valve comprising an inlet (8) connected to the catheter (4), an outlet connected to the collection bag  
10 (3) and a valve body (10) controlling the connection between the inlet and the outlet, said valve body being arranged to keep the inlet (8) closed by a resilient force and to open the inlet when a predetermined pressure is reached in the inlet, and being arranged at  
15 the inlet such that a pressure in said inlet substantially below the opening pressure of the valve, is capable of keeping said valve body in the opened position until said resilient force exceeds a force acting on the valve body, and provided by the fluid pressure in  
20 the inlet.

2. A device according to claim 1, c h a r a c -  
t e r i z e d in that the valve body (10) comprises a resilient diaphragm partially defining a chamber in which the outlet (11) opens, said diaphragm contacting  
25 a sealing bead (9) surrounding the inlet (8), to form a fluidtight seal below a certain maximum fluid pressure in the inlet (8).

3. A device according to claim 2, c h a r a c -  
t e r i z e d in that the valve (1) comprises a circular valve housing (12), in which the inlet (8) is  
30 centrally arranged and which, together with the diaphragm (10), defines said chamber, said diaphragm being tightened over the valve housing (12) to contact the sealing bead (9) resiliently.

35 4. A device according to claim 3, c h a r a c -



t e r i z e d in that the circular valve housing (12) is provided with peripheral screwthreads (13) or grooves engaged by a lid (15) provided with co-operating screwthreads or shoulders.

5           5. A device according to claim 4, c h a r a c -  
t e r i z e d in that the lid (15) comprises an in-  
ternal peripheral groove (14) in which a peripheral  
bead edge portion (10a) of the diaphragm (10) engages.

10           6. A device according to claim 1, c h a r a c -  
t e r i z e d in that the valve body is formed as a  
cup spring, or is actuated by a cup spring, which  
exerts the resilient force providing a closing action  
on the valve body.

15           7. A device according to claim 3 or 6, c h a -  
r a c t e r i z e d in that in addition to the resi-  
lient force exerted by the diaphragm and acting towards  
the inlet a further resilient force is exerted on the  
diaphragm and towards its closing position by adjustable  
mechanical spring means arranged externally of the dia-  
20 phragm.

25           8. A device according to claim 7, c h a r a c -  
t e r i z e d in that the resilient diaphragm compri-  
ses a stiffened central portion to which the force of  
said mechanical spring means is transferred.

AMENDED CLAIMS

(received by the International Bureau on 9 July 1980 (09.07.80))

1. A urine drainage device permitting training of the bladder and comprising a catheter connectable to the bladder and communicating with a collection bag, c h a r a c t e r i z e d in that the urine drainage device comprises a valve (1) for controlling the connection between the catheter (4) and the collection bag (3) said valve comprising an inlet (8) connected to the catheter (4), an outlet connected to the collection bag (3) and a diaphragm (10) controlling the connection between the inlet and the outlet, said diaphragm being arranged to keep the inlet (8) closed by a resilient force and to open the inlet when a predetermined pressure is reached in the inlet, and being arranged at the inlet such that a pressure in said inlet substantially below the opening pressure of the valve, is capable of keeping said diaphragm in the opened position until said resilient force exceeds a force acting on the diaphragm, and provided by the fluid pressure in the inlet.

2. A device according to claim 1, c h a r a c t e r i z e d in that the diaphragm (10) partially defining a chamber in which the outlet (11) opens, contacts a sealing bead (9) surrounding the inlet (8), to form a fluidtight seal below a certain maximum fluid pressure in the inlet (8).

3. A device according to claim 1 or 2, c h a r a c t e r i z e d in that the valve (1) comprises a circular valve housing (12), in which the inlet (8) is centrally arranged and which, together with the diaphragm (10), defines said chamber, said diaphragm being tightened over the valve housing (12) to contact the sealing bead (9) resiliently.

4. A device according to claim 3, c h a r a c t e r i z e d in that the circular valve housing (12)



is provided with peripheral screwthreads (13) or grooves engaged by a lid (15) provided with co-operating screwthreads or shoulders.

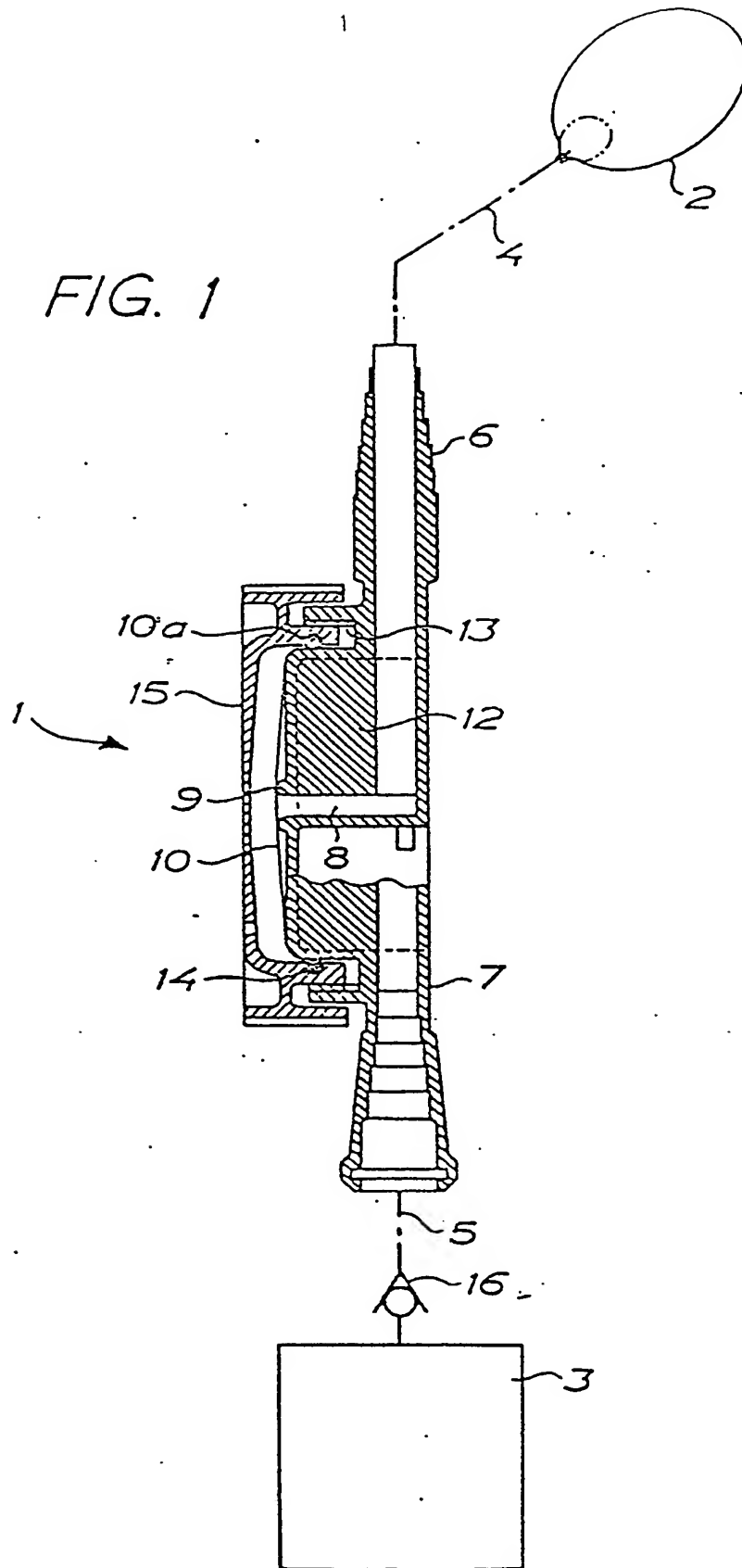
5        5. A device according to claim 4, c h a r a c -  
t e r i z e d in that the lid (15) comprises an in-  
ternal peripheral groove (14) in which a peripheral  
bead edge portion (10a) of the diaphragm (10) engages.

10       6. A device according to claim 1, c h a r a c -  
t e r i z e d in that the diaphragm is formed as a  
cup spring, or is actuated by a cup spring, which  
exerts the resilient force providing a closing action  
on the diaphragm.

15       7. A device according to claim 3 or 6, c h a -  
r a c t e r i z e d in that in addition to the resi-  
lient force exerted by the diaphragm and acting towards  
the inlet a further resilient force is exerted on the  
diaphragm and towards its closing position by adjustable  
mechanical spring means arranged externally of the dia-  
phragm.

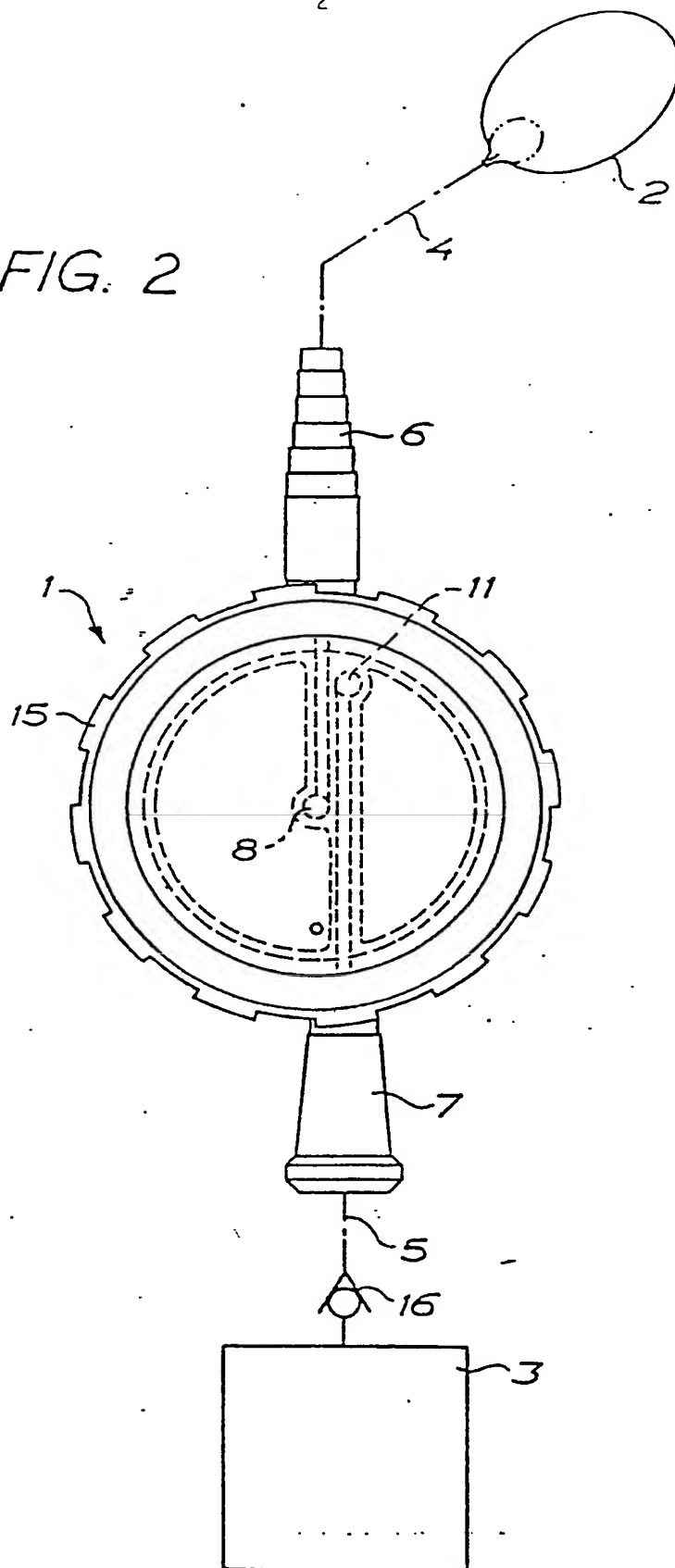
20       8. A device according to claim 7, c h a r a c -  
t e r i z e d in that the resilient diaphragm compri-  
ses a stiffened central portion to which the force of  
said mechanical spring means is transferred.

25



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FIG. 2





# INTERNATIONAL SEARCH REPORT

International Application No. **PCT/SE80/00015**

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC		
<b>A 61 F 5/44, A 61 H 21/00</b>		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
IPC	A 61 F 5/44, A 61 H 9/00, 21/00	
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US Cl	128:294, 295	
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